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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,613	04/28/2006	Alexander Cherkasky	DETR0101PUSA	9743

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EXAMINER	
KINSEY WHITE, NICOLE ERIN	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,613	CHERKASKY, ALEXANDER	
	Examiner	Art Unit	
	NICOLE KINSEY WHITE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-30* is/are pending in the application.

4a) Of the above claim(s) *21,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-20 and 22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the current drawings filed April 28, 2006 are not properly labeled (e.g., Figure 1, Figure 2, etc.). Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. **The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.**

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.

(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.

(f) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

In addition, the spacing of the lines of the specification is such as to make reading difficult. New application papers with lines 1½ or double spaced on good quality paper are required.

Claim Objections

Claims 18 and 27 remain objected to because of the following informalities: Claims 18 and 27 contain the phrase "a cleavage site for a protease.." after the period. Appropriate correction is required. Applicants are required to amend (change) the claims to address this objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20 and 28 recite that "the GFP, fluorescent regions or the membrane penetration domains include the Gene - 3 Protein of the bacteriophage fd, gp 41 or Tat protein of the HIV – 1." It is not clear how GFP, for example, can include phage or HIV-1 domains. Are these fusion proteins? Does each protein (GFP, fluorescent regions or the membrane penetration domains) contain Gene-3, gp 41 and Tat? One of ordinary skill in the art cannot determine the metes and bounds of the claims.

Response to Arguments

In the reply dated April 21, 2009, applicant argues that "a fusion protein can contain additionally either GFP or a membrane penetration domain."

Applicants need to amend (change) the claims to state that "a fusion protein can contain additionally either GFP or a membrane penetration domain." As written, the claim is confusing as stated above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 12, 14, 18, 22, 24, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al. (Journal of Neuroscience, 2002, 22(12):4964-4972).

The claims are directed to fusion proteins comprising: regions selected from the group consisting of specific antigen binding regions, microtubule binding regions, and immune response triggering regions.

Yoshida et al. discloses fusion proteins comprising tau (microtubule binding region) and GFP.

Claims 11, 12, 14, 18, 22, 24, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Chapin et al. (Journal of Cell Science, 1991, 98:27-36).

The claims are directed to fusion proteins comprising: regions selected from the group consisting of specific antigen binding regions, microtubule binding regions, and immune response triggering regions.

Chapin et al. discloses fusion proteins comprising MAP4 (microtubule binding region) and β-gal.

Claims 11-13, 15, 22, 25, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Shi et al. (Biotechnology Letters, 2003, 25(10):815-819).

Shi et al. discloses a fusion protein consisting of erbB2 single chain antibody (scFv), Fc fragment of human IgG1 and IL-2.

Claims 11, 14, 18, 22, 24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al. (Journal of Neuroscience Research, 2002, 67(5):625-633).

Zhou et al. discloses fusion proteins of human tau (microtubule binding region) with green fluorescent protein (GFP).

Claims 22, 23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobatake et al. (Journal of Biotechnology, 1995, 35:263-268).

The claims are directed to fusion proteins comprising: regions selected from the group consisting of antibody binding regions, and microtubule - binding regions, wherein the antibody binding regions include a component selected from the group consisting of Staphylococcal protein A (SPA), extracellular region of the Fc receptor CD 64, and regions thereof.

Kobatake et al. discloses fusion proteins comprising maltose binding protein and Staphylococcal protein A.

Claims 11, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehtio et al. (PNAS, 2003, 100(2):484-489).

The claims are directed to fusion proteins comprising: regions selected from the group consisting of specific antigen binding regions, microtubule binding regions, and immune response triggering regions and further comprising a cellulose binding region of the CipA protein.

Lehtio et al. discloses fusion proteins of the cellulose binding molecules (CBMs) such as CipA with a modified staphylococcal protein A (ZZ-domain).

Response to Arguments

In the reply dated April 21, 2009, applicant argues that the cited references do not teach the claimed invention and that the claimed invention is novel.

As stated previously, the claims, as written, are directed only to a fusion which can contain an antigen binding region or a microtubule region or an immune response triggering region. The fusion proteins of the cited references contain either an antigen binding region or a microtubule region or an immune response triggering region, and thus, meet the limitations of the claims as they are now written. There is no requirement in the claims that the fusion proteins inhibit cell division by binding to microtubules.

If applicant's fusion proteins contain all three (an antigen binding region, a microtubule region, and an immune response triggering region) then applicant should amend (change) the claims to state this.

For example, claims 11, 18 and 19 are directed to fusion proteins comprising: regions selected from the group consisting of specific antigen binding regions, microtubule binding regions, and immune response triggering regions and further comprising a cellulose binding region of the CipA protein.

As written, the claims are interpreted as being directed to a fusion protein containing an antigen binding region or a microtubule binding regions or an immune response triggering regions and further comprising a cellulose binding region of the CipA protein.

Lehtio et al. discloses fusion proteins of the cellulose binding molecules (CBMs) such as CipA with a modified staphylococcal protein A (ZZ-domain). The modified staphylococcal protein A (ZZ-domain) of the fusion protein is an immune response triggering region and CipA portion of the fusion protein is the cellulose binding region. Thus, the limitations of the claims are met. This is the same for the other art rejections under 35 U.S.C. §102.

Applicant needs to amend (change) the claims to clearly define what the fusion proteins contain and to distinguish the claimed fusion proteins from those in the cited references.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (Journal of Neuroscience, 2002, 22(12):4964-4972) or Chapin et al. (Journal of Cell Science, 1991, 98:27-36) or Shi et al. (Biotechnology Letters, 2003, 25(10):815-819) or Zhou et al. (Journal of Neuroscience Research, 2002, 67(5):625-633) or Kobatake et al. (Journal of Biotechnology, 1995, 35:263-268) or Lehtio et al. (PNAS, 2003, 100(2):484-489) and further in view of Whitlow et al. (U.S. Patent No. 5,856,456).

The claims are directed to fusion proteins comprising spacer or linker regions.

The cited reference do not teach spacer or linker regions. However, Whitlow et al. teaches the use of linkers and spacers between fusion partners to allow the resulting linked fusion polypeptide to properly fold into a conformation providing the desired biological activity and reduce steric hindrances.

Therefore, it would have been obvious for one of ordinary skill in the art to include spacers or linkers between fusion partners as suggested by Whitlow et al. to reduce steric hindrances and to allow the fusion partners to properly fold. There would have been a reasonable expectation of success as linkers and spacers are routinely used between fusion partners and given the successfully use of spacers and linkers by Whitlow et al.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White/
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648